Notice of Allowability	Application No. 09/068,293	Applicant(s) SANDALON ET AL.	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed 6/14/04 and the interview of 7/7/04*.

2. ☒ The allowed claim(s) is/are *1,2,4-13,16-20,22-37,41-43 and 45-50*.

3. ☒ The drawings filed on *06 May 1998 and 14 October 2003* are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *7/7/04* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Examiner's Amendment

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 07/07/04, Maria Marucci and John P. White requested an extension of time for ONE MONTH(S) and authorized the Director to charge Deposit Account No. 03-3125 the required fee of $205.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In the **Claims**:

Claim 2. (Currently Amended) The complex according to claim 1, further comprising additional SV40 protein or proteins~~, preferably SV40 agnoprotein~~.

Claim 7. (Currently Amended) The complex according to claim 6, wherein said purified exogenous circular or linear naked DNA is DNA which encodes a protein or peptide, wherein said protein or peptide is not made or contained in a mammalian cell prior to infection with the complex, or is purified exogenous naked DNA which encodes a protein or peptide, wherein said protein or peptide is made or contained in said cell in an amount insufficient for proper cell function prior to infection with the complex, or is purified exogenous naked DNA which encodes a protein or peptide, wherein said

protein or peptide is made or contained in said cell in a form inadequate for proper cell function prior to infection with the complex, or encodes a RNA.

Claim 9. (Currently Amended) The complex according to claim 1, wherein said purified exogenous naked DNA further ~~comprising~~ comprises a SV40 *ori* DNA sequence as a replication regulatory element ~~and further comprising a purified exogenous naked DNA sequence encoding~~ and one or more regulatory elements sufficient for the expression of said exogenous RNA or exogenous protein or peptide in a mammalian cell.

Claim 10. (Currently Amended) The complex according to claim 1, wherein said constituent is purified exogenous RNA, wherein said purified exogenous RNA is RNA which encodes a protein or peptide which is not made or contained in a mammalian cell prior to infection with the complex, or is purified exogenous RNA which encodes a protein or peptide which is made or contained in said cell in an amount insufficient for proper cell function prior to infection with the complex, or is purified exogenous RNA which encodes a protein or peptide which is made or contained in said cell in a form, inadequate for proper cell function prior to infection with the complex, said purified exogenous RNA having regulatory elements, ~~including~~ comprising a translation signal or signals sufficient for the translation of said protein or peptide in said mammalian cell, operatively linked thereto.

Claim 18. (Currently Amended) A method for the in vitro construction of ~~SV40 viruses or pseudoviruses~~ the infectious particle complex of claim 1 comprising the following steps:

(a) allowing a semi-purified or pure SV40 VPI capsid protein or a mixture of VPI and at least one other SV40 capsid protein to self-assemble into SV40-1ike particles; and

(b) bringing the SV40-like particles assembled in step (a) into contact with said purified ~~exogenous~~ recombinant nucleic acid constituent to give *in vitro* constructed viruses, or into contact with a vector ~~comprising said purified exogenous nucleic acid~~ of Claim 1 to give pseudoviruses, so as to thereby effect *in vitro* construction of SV40 viruses or pseudoviruses.

Claim 20. (Currently Amended) The method according to claim 18, wherein in step (a) at least one other SV40 protein~~, preferably SV40 agnoprotein,~~ is added to the mixture of said SV40 capsid protein or proteins and said purified exogenous nucleic acid.

Claim 27. (Currently Amended) The method according to claim 18, wherein in step (b) ~~SV40 *ori* DNA sequence is added and said exogenous nucleic acid has operably linked thereto a DNA sequence encoding~~ the recombinant nucleic acid constituent further comprises an SV40 *ori* DNA sequence as a replication regulatory

element and one or more regulatory elements sufficient for the expression of an exogenous protein encoded thereby in a cell.

Claim 28. (Currently Amended) The method according to claim 18, wherein said recombinant ~~exogenous~~ nucleic acid is purified exogenous RNA, wherein said purified exogenous RNA is RNA which encodes a protein or peptide, wherein said protein or peptide is not made or contained in a mammalian cell prior to infection with the complex, or is purified exogenous RNA which encodes a protein or peptide, wherein said protein or peptide is made or contained in an amount insufficient for proper cell function prior to infection with the complex, or is purified exogenous RNA which encodes a protein or peptide, wherein said protein or peptide is made or contained in said cell. in a form inadequate for proper cell function prior to infection with the complex, and wherein said purified exogenous RNA has regulatory elements, ~~including translation signal,~~ comprising a translation signal or signals sufficient for the translation of said protein in said mammalian cell, operatively linked thereto.

Claims 37. (Currently Amended) The method according to claim 35, wherein in step (a) at least one other SV40 protein~~, preferably SV40 agnoprotein,~~ is added to the semi-purified or pure SV40 VPI capsid protein or the mixture of VPI and at least one other SV40 capsid protein.

Claim 42. (Currently Amended) The infected cell according to claim 41, wherein the cell is a human cell selected from the group consisting of hemapoietic cells, muscle cells, tumor cells, nerve cells and *in vitro* germ line cells.

Add New Claims:

Claim 48. The complex of claim 2, further comprising SV40 agnoprotein.

Claim 49. The method of claim 20, wherein the at least one other SV40 protein is agnoprotein.

Claim 50. The method of claim 37, wherein the at least one other SV40 protein is agnoprotein.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76. The Declaration identifies the Residence of each inventor but the Post Office Address is blank.

The Abstract is over 150 words and uses legal terminology (i.e. said) and has been amended as follows (on a separate page):

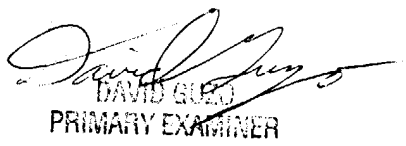
Abstract

The invention relates to constructs capable of infecting mammalian cells comprising at least one semi-purified or pure SV40 capsid protein and a constituent selected from the group consisting of an exogenous DNA, a vector comprising an exogenous DNA, an exogenous RNA, a vector comprising an exogenous RNA, an exogenous protein or peptide product, and antisense RNA, ribozyme RNA or any RNA or DNA which inhibits or prevents the expression of undesired protein(s) in ~~said~~ the mammalian cell and optionally further comprising operatively linked regulatory elements sufficient for the expression and/or replication of ~~said~~ the exogenous protein in a mammalian cell. ~~The protein product is preferably a therapeutic protein or peptide product which is not made or contained in mammalian cells, or is made or contained in such cells in abnormally low amount, or is made or contained in such cells in defective form, or is made or contained in mammalian cells in physiologically abnormal or normal amount and can be an enzyme, a receptor, a structural protein, a regulatory protein or a hormone.~~ The invention further relates to a method for the *in vitro* construction of SV40 viruses or pseudoviruses constructs according to the invention. ~~In a further aspect the invention relates to mammalian, preferably human cells infected with the constructs of the invention or with constructs obtained by any of the methods of the invention. Still further, the invention relates to a method of providing a therapeutic DNA, RNA, protein or peptide product or antisense RNA to a patient in need of such product by administering to the patient a therapeutically effective amount of the SV40 viruses or pseudoviruses of the invention or a therapeutically effective amount of infected cells according to the invention. Pharmaceutical compositions comprising as active ingredient a therapeutically effective amount of the SV40 viruses or pseudoviruses according to the invention or a therapeutically effective amount of infected cells according to the invention are also within scope of this application.~~

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David Guzo
July 7, 2004